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Certifier <i>SNR</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0314]

Prescription Drug Products; Levothyroxine Sodium; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is announcing that manufacturers who were marketing orally administered drug products containing levothyroxine sodium on or before August 14, 1997, may continue to market these products without approved applications until August 14, 2001. FDA is extending by 1 year the compliance date given in the notice published in the **Federal Register** of August 14, 1997 (62 FR 43535). The agency is taking this action to give manufacturers additional time to conduct studies and to prepare applications.

EFFECTIVE DATE: *[Insert date of publication in the Federal Register.]*

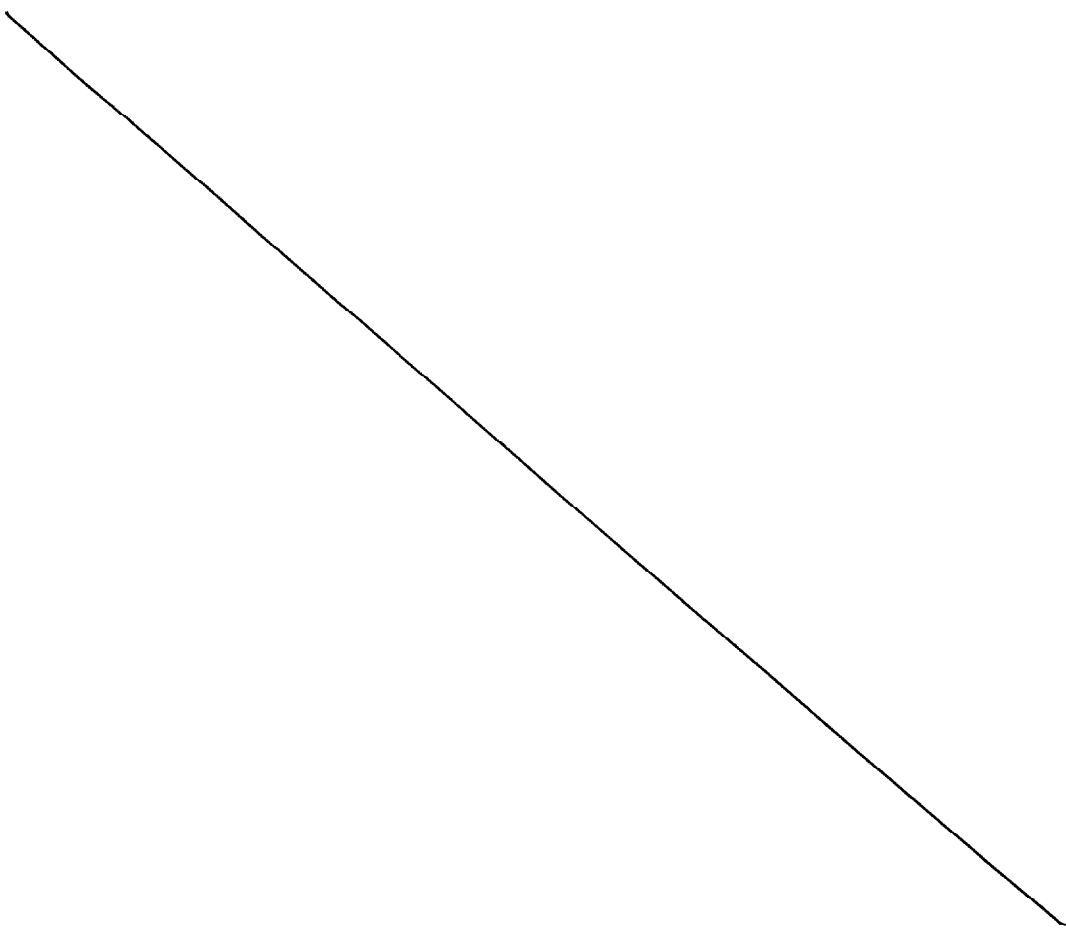
FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 1997 (62 FR 43535), FDA announced that orally administered drug products containing levothyroxine sodium are new drugs and required manufacturers to have approved applications as a condition of marketing. The notice advised that manufacturers who were marketing levothyroxine sodium drug products on or before August 14, 1997, may continue to market their products until August 14, 2000.¹ The notice stated

¹ After August 14, 1997, a new levothyroxine drug product may not be introduced into the market unless FDA has approved an application for that product.

that a manufacturer who marketed a levothyroxine sodium drug product without an approved application after that date would be subject to regulatory action.

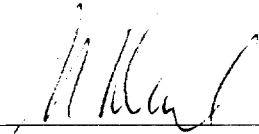
FDA permitted this period of continued marketing because it regards levothyroxine sodium products as medically necessary and, therefore, wanted to allow sufficient time for manufacturers to conduct the required studies and to prepare and submit applications, as well as to allow the agency sufficient time to review these applications. FDA has now concluded that manufacturers may need additional time to conduct studies and to prepare applications. Therefore, the agency extends by 1 year the compliance date given in the **Federal Register** notice of August 14, 1997, to permit continued marketing of these products until August 14, 2001.



This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505 (21 U.S.C. 352, 355)) and under authority delegated to the Associate Commissioner for Regulatory Affairs (21 CFR 5.20).

Dated:

April 18, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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